

Translation

PATENT COOPERATION TREATY

PCT/JP2003/007478



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A31384A	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/007478	International filing date (day/month/year) 12 June 2003 (12.06.2003)	Priority date (day/month/year) 12 June 2002 (12.06.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/765, 31/22, 31/365, A61P 17/14, 39/02, C07D 323/00, C08G 63/78, 63/08, C07C 67/00, 69/68, C08L 67/04		
Applicant AMATO PHARMACEUTICAL PRODUCTS, LTD.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of _____ sheets.
- This report contains indications relating to the following items:
 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☒ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 12 June 2003 (12.06.2003)	Date of completion of this report 22 March 2004 (22.03.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP2003/007478

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-8, 10	YES
	Claims	1-4, 9	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 2000-239171 A (Tokai Education Instruments Co., Ltd.), 05 September 2000

Document 2: WO 01/21612 A1 (Amato Pharmaceutical Products Ltd.), 29 March 2001

Document 3: WO 01/21182 A1 (Amato Pharmaceutical Products Ltd.), 29 March 2001

Claims 1-4 and 9 pertain to inhibitors of the side effects from anti-cancer drugs and hair-loss inhibitors, which comprise a mixture of cyclic and/or chain polylactic acids that exhibit a degree of condensation between 3-20. Document 1 (abstract, claims, paragraphs [0002] to [0004]) discloses QOL-improving agents which comprise a mixture of cyclic and/or chain polylactic acids that exhibit a degree of condensation between 3-20, and indicates that said QOL improvers inhibit the loss of hair due to the side-effects of anti-cancer agents. Thus, the inventions that are set forth in claims 1-3 and 9 are disclosed in document 1; therefore, they lack novelty.

Claims 5-8 and 10 pertain to the production of the abovementioned polylactic acid mixtures via a specific production method or to food and drink products that contain the abovementioned medicaments, and these inventions are not disclosed in document 1. However,

document 2 (abstract, claims) and document 3 (abstract; claims; page 11, line 24 to page 15, line 12) disclose mixtures of cyclic and/or chain polylactic acids that exhibit a degree of condensation between 3-20, which are produced via the abovementioned specific production method; therefore, a person skilled in the art could easily conceive of substituting the polylactic acid mixtures that are disclosed in documents 2 and 3 for those that are disclosed in document 1 as the polylactic acid mixtures in the medicaments comprising a mixture of cyclic and/or chain polylactic acids that exhibit a degree of condensation between 3-20, which are disclosed in document 1. Furthermore, in the technical field related to medicaments, it is common practice to introduce such medicaments into a food or drink product. Consequently, claims 5-8 and 10 do not involve an inventive step.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 02/074835 A1 [EY]	26 September 2002 (26.09.2002)	18 March 2002 (18.03.2002)	19 March 2001 (19.03.2001)
WO 03/007937 A1 [EY]	30 January 2003 (30.01.2003)	17 July 2002 (17.07.2002)	18 July 2001 (18.07.2001)

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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